OCT 1 8 2000

K002921

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1) **Submitter's name, address, and contact person:**

Hosuk Co., Ltd
52-6 Dukjeong-Ri, Samsung-Myun, Umsung-Gun, Chungcheong Province, Korea
Contact: Mr. Y. H. Kim / Manager, Quality Management Section
TEL: +82-43-883-0411 / FAX: +82-43-883-0414

2) **Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:**

Common/Usual Name:
Insulin Syringe

Proprietary Name:
Sureone disposable insulin syringe

Classification Name	Class	Panel	Product Code
Insulin Syringe	II	80	FMF - Piston Syringe

3) **Identification of the predicate or legally marketed device:**
Hosuk Company believes that the SureOne Insulin Syringe is substantially equivalent to the currently marketed B-D Insulin Syringe, K980580.

4) **Device Description:**
The **sureone** disposable insulin syringe is used for subcutaneous injection of U-100 Insulin. This device is sterile, single use, disposable hypodermic syringe with permanently affixed hypodermic needle. The **sureone** disposable insulin syringe consists of a syringe barrel, a plunger rod, and a hypodermic needle permanently bonded to the tip of the syringe with epoxy. The **sureone** disposable insulin syringes are available in 1cc, 1/2cc and 3/10cc syringe capacities with the following sizes of hypodermic needle: 28 GAUGE x 1/2", 29 GAUGE x 1/2" and 30 GAUGE x 3/10".

The Sureone disposable insulin syringe meets the following standards;
ISO 8537, Sterile, Single-Use Syringes, with or without Needle, for Insulin
ISO 9626, Stainless Steel Needle Tubing for Manufacture of Medical Devices

5) **Intended Use**:
The **sureone** Insulin Syringe is intended for the injection of insulin.

6) **Substantial Equivalence**:
The **sureone** Disposable Insulin Syringe submitted in this 510(k) is substantially equivalent in intended use, technology/principles of operation, materials and performance to the cleared B-D Insulin Syringe (K955235 and K980580), and Monoject Insulin Syringe(K851090 and K991758).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2000

Hosuk Company Limited
C/O Mr. Mark Job
Responsible Third Party Offical
TUV Product Service Incorporated
1775 Old Highway 8
New Brighton, Minnesota 55112

Re: K002921
Trade Name: Sureone Insulin Syringe
Regulatory Class: II
Product Code: FMF and FMI
Dated: October 3, 2000
Received: October 4, 2000

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: TBD

Device Name: SureOne Insulin Syringe

Indications For Use: Insulin syringes are intended **ONLY** for the injection of "**U-100**" insulin.

Please do not write below this line.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cuccinta

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K002921